This material is an English translation of the press release announced on July 25, 2016 in Japanese, and the Japanese release is given priority about the content and the interpretation.

July 25, 2016

Notification of the results of Phase II clinical study of HP-3150 in Japan for "Lower back pain" (an analgesic transdermal drug containing NSAIDs)

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu city, Saga prefecture, Japan; Chairman and CEO: Hirotaka Nakatomi, hereinafter referred to as Hisamitsu) hereby announces the results of the Phase II clinical study for "Lower back pain" in Japan for an analgesic transdermal patch containing NSAIDs (Development code: HP-3150, hereinafter referred to as "the product").

In the Phase II clinical study, the efficacy and safety of administration of the product were compared with a placebo in patients with "Lower back pain". As a result, a statistically significant difference was confirmed for improvement in the primary efficacy endpoint compared with the placebo group. For safety, no serious adverse reactions were observed.

The product is a systemic transdermal drug developed utilizing Hisamitsu's TDDS (Transdermal Drug Delivery System) technology and containing the active ingredient NSAIDs (Non-Steroidal Anti-Inflammatory Drugs).

Hisamitsu expects the product to be a new option for the treatment of "Lower back pain" by realizing its long-lasting effect by means of maintaining a stable blood drug concentration.

A Phase II/III of the product(clinical study compared with a placebo) is being conducted for "cancer pain".

Hisamitsu aim to initiate a Phase III clinical study during FY 2017.